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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,226	09/21/2001	David Richard Rose	12243.19USU1	5874

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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,226	ROSE ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-48 are pending as amended by a preliminary amendment filed on September 21, 2001.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-22, drawn to mannosidase II crystals, classified in class 435, subclass 201.

II. Claims 23-24, drawn to media storage of crystal data for mannosidase II, classified in class 702, subclass 27.

III. Claims 25-26 and 30-34, drawn to methods of screening for a ligand or modulator using a mannosidase II crystal structure, classified in class 702, subclass 27.

IV. Claims 27-29, 35-36, and 39-40, drawn to ligands and modulators of mannosidase II, classified in class 514, subclass 12.

V. Claim 37, drawn to methods of designing mannosidase II inhibitors using a mannosidase II crystal structure, classified in class 702, subclass 27.

VI. Claim 38, 41-42 and 48, drawn to using a mannosidase ligand in treatment, classified in class 514, subclass 12.

VII. Claim 43, drawn to methods of determining an unknown polypeptide's structure using the structure of mannosidase II, classified in class 702, subclass 27.

VIII. Claims 44-47, drawn to vectors, host cells, and methods of making mannosidase II, classified in class 435, subclass 201.

3. The inventions are distinct, each from the other because of the following reasons:

The products of Group I and II are related because the data of Group II describe the crystal of Group I. However, these products are distinct because they have distinct structures

and functions. The crystal is a protein comprised of amino acids while the data are on a computer readable media. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to the methods of Groups III, V, and VII because it is the representation of the crystalline protein of Group I that is used in the methods of Groups III, V, and VII. However, the crystal itself is neither used nor produced in the claimed methods. Thus, Group I is patentably distinct from Groups III, V, and VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The products of Group I and IV are related because the compounds of Group IV interact with the proteins of the crystal of Group I. However, these products are distinct because they have distinct structures and functions. The crystal is a protein comprised of amino acids while the compounds are small organic molecules of any composition. Thus, Groups I and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to the methods of Group VI because the ligands used in the methods bind to the protein of the crystal of Group I. However, the crystal itself is neither used nor produced in the claimed methods. Thus, Group I is patentably distinct from Group VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in

the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The vector of Group VIII is related to the protein crystals of Group I by virtue of the fact that the DNA encode the proteins. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because they are wholly different in structure and function. A DNA's structure is comprised of nucleotides while a protein's structure comprised of amino acid; the DNA's function is to encode a protein while this protein's function is to catalyze the mannosidase reaction. Therefore, Group I is patentably distinct from Group VIII. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VIII, restriction for examination purposes as indicated is proper. While Groups I and VIII can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group I, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I and VIII have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Group II is related to Groups III, V, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the crystal structure data can be used for a materially distinct process of using the product, such as in methods to produce mannosidase variants of higher activity. This is a distinct process from any of the methods of Groups III, V, or VII because a distinct product is produced, that is an enzyme and not a ligand, and inhibitor, or a novel 3D structure as is the case for Groups III, V, and VII, respectively. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups III, V, or VII, restriction for examination purposes as indicated is proper.

The products of Group II and IV are related because the compounds of Group IV interact with the proteins defined by the crystal structure data of Group II. However, these products are distinct because they have distinct structures and functions. The data is on a computer readable medium while the compounds are small organic molecules of any composition. The data has no particular function while the function of the compounds is to bind the mannosidase protein and alter its activity. Thus, Groups II and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group II is related to the methods of Group VI because the ligands used in the methods bind to the protein of the crystal described by the data of Group II. However, the data itself is neither used nor produced in the claimed methods. Thus, Group II is patentably distinct from Group VI. Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The crystal structure data of Group II is related to the vector of Group VIII because the data describe the crystal structure of the protein encoded by the vector. However, these products are distinct by virtue of distinct structures and functions. The data is on a computer readable medium while the vector is made of nucleotides. The data has no particular function while the function of the vector encodes a protein that can be expressed in a host cell. Thus, Groups II and VIII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Group III and the products of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for a materially different process of using the product, such as in random screening for mannosidase ligands in the absence of crystal structure data. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups III, V and VII are all related as methods of using crystal structure data of mannosidase. Each of these methods is distinct from the others because they involve

distinct steps to produce distinct products. The methods of Group III involve using a crystal structure to direct screening of compounds while the methods of Group V are specifically drawn to designing compounds to fit a space. Group VII is drawn to solving novel crystal structures using the coordinates of the disclosed mannosidase crystals; steps to complete such task involve neither screening (Group III) nor designing inhibitors (Group V), but involve overlaying a related protein, of unknown structure, onto the structure disclosed. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group V is not required for Group VII, restriction for examination purposes as indicated is proper.

Groups III and VI are related as methods of using a ligand of mannosidase. However, these methods are distinct based on their wholly distinct method steps to produce distinct outcomes. Method steps of Group III involve computer and/or wet-chemistry screening of mannosidase activity while the methods of Group VI involve treatment of living organisms. Thus, Groups III and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups III and V are related to Group VIII because the enzyme, for which ligands/inhibitors are screened in the methods of Groups III and V, is encoded by the vector of Group VIII. However, the vector is neither used nor produced in the claimed methods. Thus, Groups III and V are patentably distinct from Group VIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group IV is related to the methods of Group V because the ligands of Group IV would bind the protein modeled in the methods of Group V for which inhibitors are being designed. However, inhibitors are a specific subset of ligands and/or modulators not intended in the products of Group IV. Thus, Group IV is patentably distinct from Group V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the ligands can be used for a materially different process of using the product, such as in purification column procedures for purifying mannosidase. Thus, Groups IV and VI are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group VI, restriction for examination purposes as indicated is proper.

Groups IV and VII are related because the ligands of Group IV bind mannosidase and the mannosidase structure is used in Group VII. However, the ligands are neither made nor used in the methods. Thus, Groups IV and VII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV and VIII are related because the ligands of Group IV bind a protein encoded by Group VIII. However, these are distinct products with distinct structures and functions. Ligands are any small molecule with particular binding properties while vectors are polynucleotides. Ligands function to bind mannosidase while vectors encode mannosidase. Thus, Groups IV and VIII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups V and VI are methods related to mannosidase inhibitors or ligands. These methods are distinct having distinct method steps to produce distinct products. Thus, Groups V and VI are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VI and VII are related as methods related to mannosidase. However, these methods are distinct based on their wholly distinct method steps to produce distinct outcomes. Method steps of Group VI involve treatment of living organisms while the methods of Group VII determine a protein molecule's structure. Thus, Groups VI and VII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VI and VIII are related because the ligand used in the methods of Group VI binds a protein encoded by the vector of Group VIII. However, the vector is neither used nor made in the methods. Thus, Groups VI and VIII are patentably distinct. Because these inventions are

distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group VII is related to Group VIII because the standard structure for the method of Group VII is of a protein encoded by the vector of Group VIII. However, the vector is neither used nor made in the methods. Thus, Groups VI and VIII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Conclusion

5. Complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen M Kerr
Examiner
Art Unit 1652

June 11, 2004